

REMARKS

By this Amendment, claims 3 and 10 are canceled without prejudice or disclaimer, claims 1, 2, 6, 11, 12, and 14 are amended, and claims 37-46 are added. Consequently, claims 1, 2, 6-9, 11-46 are currently pending in this application.

As an initial matter, Applicants wish to take this opportunity to thank the Examiner for reconsidering the restriction requirement of March 22, 2006 and retaining all of the pending claims for further examination.

As another initial matter, Applicants respectfully note that the Office Action lacks clear indication of the status of claim 6. Although claim 6 is indicated in the Office Action Summary as being rejected, that claim is not subject to any of the rejections in the Office Action. Thus, Applicants assume that claim 6 contains allowable subject matter. If, however, the Examiner intended a rejection of claim 6, Applicants respectfully request that the Examiner set forth a detailed explanation of that rejection and make any subsequent Office Action non-final in order to provide Applicants with a full and fair opportunity to respond.

For the following reasons, Applicants respectfully request reconsideration and withdrawal of all of the rejections outstanding in the July 31, 2006 Office Action.

35 U.S.C. § 102 Rejection

Claims 1, 2, 3, 15, 16, 18, 19, and 21 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,344,454 to Clarke et al. ("Clarke"). Although Applicants do not necessarily agree with this rejection, Applicants note that claim 10, among other dependent claims, is not included in this rejection. Applicants therefore have amended independent claim 1 to recite the subject matter of claim 10 (i.e., the protective liner being removably attached to at least one of the substrate and the sheet

of tissue). For at least this reason, independent claim 1 and its dependent claims patentably distinguish from Clarke. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103 Rejection Based on Binette

Claims 1-4¹, 7-16, and 18-21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 6,994,428 to Binette et al. (“Binette”). As explained below, this rejection should be withdrawn.

Independent claim 1, as amended, recites “a substrate having a first surface and a second surface opposite to the first surface,” “a sheet of tissue attached to the first surface of the substrate,” and “a protective liner removably attached to at least one of the substrate and the sheet of tissue to cover the sheet of tissue.”

Binette discloses a reinforced foam implant for repairing orthopaedic type tissue injuries (e.g., meniscus, ligaments, and tendons). The implant 10 includes a foam component 12 and a reinforcement component 14 integrally formed with the foam component 12. In the embodiment shown in Fig. 3, the implant 10 includes a barrier layer 16 fused to the top and/or bottom surface of the foam component 12. The barrier layer 16 acts as a barrier to hyperplasia and tissue adhesion. See, e.g., col. 16, lines 36-45, of Binette. The Office Action contends that the foam component 12 and element 11 of Binette allegedly correspond to the recited “substrate” and “tissue implant,” respectively. The Office Action also contends that the barrier layer 16 allegedly corresponds to the recited “protective liner.”

¹ Applicants note that claim 4 was not pending at the time of the Office Action.

Binette, however, does not teach or suggest, among other things, “a protective liner removably attached to at least one of the substrate and the sheet of tissue,” as recited in claim 1. Instead, as mentioned above, the barrier layer 16 is fused to the foam component 12 and therefore not removable from the foam component 12.

In addition, Binette does not teach or suggest, among other things, “a sheet of tissue attached to the first surface of the substrate,” as recited in claim 1. While the Office Action contends that element 11 of Binette allegedly corresponds to the recited “tissue implant,” element 11 is not described in Binette and is therefore unclear as to what it encompasses. Regardless of this ambiguity, Applicants respectfully note that element 11 cannot correspond to the recited “sheet of tissue” at least for the reason that element 11 points to the foam component 12. Although Binette discloses its tissue patch 10 may include a biological component, there is no teaching that the biological component includes a sheet of tissue.

For at least these reasons, independent claim 1 and its dependent claims patentably distinguish from Binette. Thus, reconsideration and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103 Rejection Based on Binette and Naimark

Claims 17 and 22-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Binette in view of U.S. Patent No. 6,893,431 to Naimark et al. (“Naimark”). Each of claims 17 and 22-24 depends, either directly or indirectly, from independent claim 1. As discussed above, independent claim 1 patentably distinguishes from Binette. Naimark also does not cure the deficiency of Binette. Therefore, claims 17 and 22-24 patentably distinguish from the alleged combination of

Binette and Naimark at least by virtue of their dependency from independent claim 1.

Thus, reconsideration and withdrawal of this rejection is respectfully requested.

35 U.S.C. § 103 Rejection Based on Binette, Naimark, and Podolsky

Claims 25-36 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Binette in view of Naimark and further in view of WO 02/085402 to Podolsky (“Podolsky”). Applicants respectfully traverse this rejection.

Independent claim 25 is directed to a method of treating a lesion in a lumen of patient’s body. The method includes, among other things, “providing a tissue patch having a tissue implant attached to a substrate and a protective liner covering at least a portion of the tissue implant,” “forming the tissue patch into a contracted state,” “inserting the tissue patch in the contracted state into a lumen containing the lesion,” “removing the protective liner to reveal the tissue implant,” and “placing the tissue implant in the lesion.” As discussed below, the Office Action’s alleged combination of Binette, Naimark, and Podolsky fails to establish a *prima facie* case of unpatentability under 35 U.S.C. § 103(a).

The Office has the initial burden of presenting a *prima facie* case of unpatentability. To establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a), three basic criteria must be met. First, the prior art references when combined must teach or suggest all the claim elements. Second, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Finally, there must be a reasonable expectation of success. See M.P.E.P. § 2143. Furthermore, case law in this context indicates that the teaching or

suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and that the evidence of a teaching, suggestion, or motivation to combine must be “clear and particular.”

As an initial remark, Applicants note that the Office Action fails to specifically point out how the alleged combination teaches all of the method recitations of claim 25. While the Office Action alleges that “[t]he modified Binette et al. meets the claim limitations as described above except for some of the specific steps of placing the tissue patch in the lesion,” it is unclear as to what the so-called “modified Binette et al.” teaches since it was never described in the Office Action with respect to the specific method recitations of claim 25.

Regarding the first criterion, the Office Action’s alleged combination of Binette, Naimark, and Podolsky would not teach all of the subject matter of claim 25. For example, notwithstanding the ambiguity noted above and contrary to the Office Action’s allegation, none of the cited references, either taken alone or in combination, teaches or otherwise suggests, among other things, removing a protective liner (that covers at least a portion of a tissue implant) to reveal the tissue implant, as recited in claim 25. The Office Action alleges that the barrier layer 16 of Binette allegedly corresponds to the recited “protective liner.” The barrier layer 16, however, is not removable since, as discussed above, it is fused to the foam component 12. Even assuming, for the sake of argument, that the barrier layer 16 is removable, none of the cited references teaches or otherwise suggests removing the barrier layer 16 of Binette.

Moreover, none of the cited references, either taken alone or in combination, teaches or otherwise suggests, among other things, “forming the tissue patch [having a

tissue implant attached to a substrate and a protective liner covering at least a portion of the tissue implant] into a contracted state.” While Naimark discloses a retractable patch 20, the Office Action does not allege that this patch includes a “tissue implant attached to a substrate and a protective liner covering at least a portion of the tissue implant.” Instead, the Office Action alleges that the tissue implant 10 of Binette is the one that includes the recited “tissue implant” and “protective liner.” Binette, however, does not teach that the tissue implant 10 is foldable. In fact, the tissue implant 10 does not appear to be foldable because of the presence of a reinforcement component 14 which provides structural support for the damaged tissue.

For at least for these reasons, the first criterion for a *prima facie* case of obviousness has not been met.

As to the second criterion, there is no suggestion or motivation in the cited references to combine or modify the alleged teachings of the references in the manner proposed by the Office Action. The motivation alleged by the Office Action is to achieve “optimal achievement or lesion treatment.” The Office Action, however, does not provide any sufficient evidence to support that the alleged combination would result in “optimal achievement or lesion treatment.” As is apparent, the alleged motivation is merely conclusory and does not provide sufficient legal reasoning as to why the alleged combination in the manner proposed by the Office Action would have been desired by one of ordinary skill in the art. To the contrary, the alleged combination would not have been desired because, among other reasons, the tissue implant 10 of Binette is not foldable and its barrier layer 16 is not removable, as discussed above. Furthermore, removing the barrier layer 16 would necessarily destroy the teachings of Binette.

because the barrier layer 16, after being implanted, acts as a barrier to hyperplasia and tissue adhesion.

Applicants respectfully submit that the Office Action's alleged motivation clearly reflects impermissible hindsight gleaned from the present application. When the references are viewed without such hindsight, the alleged combination of the references would not have been suggested since there is no "clear and particular" suggestion or motivation to make the proposed combination or modification. Therefore, the second criterion for a *prima facie* case of obviousness also has not been met.

As to the third criterion, the alleged combination of the cited references does not show a reasonable expectation of success because, as discussed above, it is unclear as to, among other things, how the tissue patch 10 of Binette is folded into a contracted state or how the barrier layer 16 of Binette is removed. For at least these reasons, the third criterion for a *prima facie* case of obviousness also has not been met.

For at least these reasons, a *prima facie* case of obviousness has not been properly established. Therefore, reconsideration and withdrawal of this rejection under 35 U.S.C. § 103(a) based on Binette, Naimark, and Podolsky is respectfully requested.

New Claims 37-45

Independent claim 37 recites, among other things, "a substrate having a first surface and a second surface opposite the first surface," "a tissue implant attached to the first surface of the substrate and occupying a first area of the first surface, "a protective liner attached to the first surface of the substrate so that the tissue implant is placed between the substrate and the protective liner," and "an adhesive material for attaching the protective liner to the substrate, wherein the adhesive material occupies a

second area of the first surface that is different from the first area." The cited references, either taken alone or in combination, do not teach or otherwise suggest the subject matter of claim 37. Thus, claim 37 and its dependent claims patentably distinguish from the cited references.

Conclusion

Applicants respectfully request reconsideration of this application, withdrawal of all of the outstanding rejections, and allowance of all pending claims.

The Office Action contains a number of statements and characterizations regarding the claims and the related art. Applicants decline to necessarily subscribe to any statement or characterization in the Office Action, regardless of whether it is addressed above.

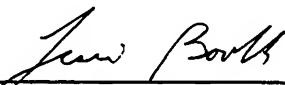
Should the Examiner wish to discuss this case, he is invited to call the undersigned at 202-408-4140.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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